K091339

CooperVision®

1. **Owner's Name & Address:**

CooperVision, Inc.
6140 Stoneridge Mall Road, Suite 500
Pleasanton, CA 94588

JAN – 5 2010

2. **Contact Person:**

Lisa Hahn
Director, Global Regulatory Affairs
CooperVision, Inc.
1215 Boissevain Avenue
Norfolk, VA 23507

Telephone (757) 664-2421
Facsimile (866) 890-1584

3. **Date Prepared:**

April17, 2009

4. **Device Identification:**

- Trade Name: Biomedics® 55 (ocufilcon D)
- Common Name: Soft (Hydrophilic) Contact Lenses
- Classification Names: Lenses, Soft Contact, Daily Wear (21 CFR 886.5925, Product Code LPL)

  Lens, Contact, (Disposable) (21 CFR 886.5925, Product Code MVN)

K091339

5. **Legally Marketed Devices to Which CooperVision, Inc. is Claiming Equivalence:**

Substantial Equivalence Table

	MODIFIED DEVICE ocufilcon D	UNMODIFIED DEVICE K972303 ocufilcon D
Material USAN Name	ocufilcon D	ocufilcon D
FDA Category (Group)	Group II Non-Ionic High Water	Group II Non-Ionic High Water
Indication for Use	Daily Wear for Frequent/Planned Replacement Wear or for Daily Disposable Wear	Daily Wear for Frequent/Planned Replacement Wear or for Daily Disposable Wear
Water Content	55%	55%
DK (cm^2/sec) ml O_2/ml x mm Hg at 35°C (Fatt method)	19.6×10^{-11}	19.6×10^{-11}
Light Transmittance	>95%	>95%
Refractive Index	1.41	1.41
Manufacturing Method	Cast-Molded	Cast-Molded
Sterilization	Steam	Steam
Packaging	Blister Pack	Blister Pack
Blue Handling Tint	Yes Entrapment Dye	Yes Entrapment Dye
Surfactant in the Final Product Saline	Yes	None

6. **Standards**

No applicable mandatory performance standards or special controls exist for this device.

7. Device Description

The lenses, Biomedics® 55 (ocufilcon D) soft (hydrophilic) contact lenses, are a hemispherical shell available in a spheric, aspheric, toric or multifocal design, intended for daily wear for frequent/planned replacement wear or for single use daily disposable wear. The lens material is equivalent to other ocufilcon D daily wear soft (hydrophilic) contact lenses cleared under several predicate device 510(k) Premarket notifications.

The lenses are in-monomer tinted from edge to edge for visibility purposes with Vat Blue 6.

The Biomedics® 55 (ocufilcon D) soft (hydrophilic) contact lenses are available as sphere, asphere, toric or multifocal lenses with the following dimension ranges:

- Chord Diameter: 12.5 to 18.0 mm
- Center Thickness 0.025 to 0.40 mm (varies with power)
- Base Curve: 6.50 mm to 10.8 mm
- Spherical Powers: -20.00 D to +20.00 D
- Add Powers: +0.25 D to +3.00
- Cylinder Powers: -0.25 to –10.00 D
- Axis 1° to 180°

The physical properties of the lenses are:

- Refractive Index at 25°C 1.41
- Oxygen Permeability (Dk) 19.6×10^{-11} (cm^2/sec) ml O_2/ml x mm Hg at 35°C (Fatt method)
- Light Transmittance >95%
- Water Content 55 %

8. Predicate Devices Information:

The modified device includes sphere/asphere, toric and multifocal configurations. The predicate devices are as follows:

Predicate Devices Information	The predicate devices are the ocufilcon D Daily Wear Soft Contact Lenses: K972303, August 20, 1997; K012425, October 12, 2001; K020193, February 28, 2002; and P890023/S004, August 28, 1996;

9. Nonclinical Tests Performed:

Physiochemical and toxicological studies were conducted as applicable to support a determination of substantial equivalence.

10. Conclusions of NonClinical Tests Performed:

- **Physiochemical:**

  The physical, optical and chemical properties of this lens remain unchanged from the unmodified device, and are within established specifications for the lenses.

- **Toxicology:**

  Results from in-vivo and in-vitro studies were conducted and verify that the lenses remain non-toxic and are biocompatible with the ocular environment.

11. Clinical Studies:

The technical characteristics, formulation, manufacturing, and sterilization processes of this lens are equivalent to ocufilcon D soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

12. Conclusion:

The device will be manufactured according to specified process controls and an established quality assurance program. The device will undergo the same manufacturing, packaging and sterilization procedures as the unmodified device currently marketed by CooperVision, Inc. The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

CooperVision, Inc.
c/o Ms. Lisa Hahn
Director, Global Regulatory Affairs
1215 Boissevain Avenue
Norfolk, VA 23507

JAN - 5 2010

Re: K091339
Trade/Device Name: Biomedics® 55% (ocufilcon D) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: II
Product Code: LPL, MVN
Dated: December 11, 2009
Received: December 14, 2009

Dear Ms. Hahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K091339**

Device Name: **Biomedics® 55 (*ocufilcon D*) Soft (Hydrophilic) Contact Lens for Daily Wear for Frequent/Planned Replacement Wear or Daily Disposable Wear**

Indications for Use:

Spherical and Aspherical - Biomedics 55 (ocufilcon D) SPHERE and ASPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from - 20.00D to +20.00D diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

Toric - Biomedics 55 (ocufilcon D) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from –20.00 to +20.00 diopters and astigmatic corrections from –0.25 to –5.00 diopters.

Multifocal - Biomedics 55 (ocufilcon D) MULTIFOCAL lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +10.00 diopters and with add powers from +0.25 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 0.75 diopters or less that does not interfere with visual acuity.

The Biomedics 55 (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for single use daily disposable wear or for planned replacement. As prescribed for single use daily disposable wear, patients are instructed to dispose of the lens at each removal. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND /OR Over-the-counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091339